Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte YASMIN THANAVALA, CHARLES JOEL ARNTZEN and HUGH S. MASON

Appeal No. 2002-1543[1]
Application No. 09/420,695

DKT KRB 3/18/04

ON BRIEF

Before WINTERS, SCHEINER and MILLS, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 1 and 4-18, the only claims remaining in the application.

Claim 1 is representative:

1. A method for providing a serum IgM and IgG response specific to hepatitis B surface antigen (HBsAg), in an animal by feeding the animal with a substance comprising a physiologically acceptable plant material containing hepatitis B surface antigen in combination with an adjuvant, said combination causing serum IgM and IgG responses specific to HBsAg in excess of serum IgM and IgG responses to HBsAg caused by HBsAg alone.

[1] As a preliminary matter, we note that this appeal is related to an appeal in application serial no. 09/464,416 (Appeal No. 2002-1901). We have considered the two appeals together.

The references relied on by the examiner are:

Arntzen et al. (Arntzen)	5,914,123	Jun. 22, 1999
Koprowski et al. (Koprowski)	5,935,570	Aug. 10, 1999

Stites et al. (Stites), in Basic and Clinical Immunology, 7th Ed., Appleton & Lange, USA, pp. 102 and 723-741 (1991)

Claims 1 and 4-18 stand rejected under 35 U.S.C. § 103 as unpatentable over Arntzen, Koprowski and Stites.

We reverse.

DISCUSSION

Arntzen describes vaccinating animals against hepatitis B by feeding them transgenic plant material containing hepatitis B surface antigen (HBsAg), but does not describe administering the oral vaccine in combination with an adjuvant. The examiner argues that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the claimed invention by adding an adjuvant to the plant material taught by Arntzen" (Answer, page 5) because both Koprowski and Stites teach that "delivery of a vaccine in combination with an adjuvant facilitates and improves its immunological therapeutic activity," while Koprowski (according to the examiner) describes "oral delivery of plant material expressing a viral antigen in combination with an adjuvant" (id., page 6).

Viewing Koprowski and Stites in their entirety, however, we cannot agree that either reference would have suggested combining an adjuvant with an oral vaccine. Koprowski describes synthesis of bioactive compounds, including immunogenic compounds, in plants infected with transformed Clavibacter xyli. According to

Koprowski, "[t]he route of administration . . . can be either parenteral or through any mucosal surface, including the oral pharynx, nasal cavity and digestive tract" (column 5, lines 43-45) "[W]here there is no [ ] purification step or steps, the bioactive compound . . . is normally administered . . . by feeding (i.e., oral route of administration) [the raw plant] to the animal" (column 5, lines 50-56). Koprowski does teach that adjuvants can facilitate or improve the immunogenic activity of the bioactive compound (column 6, lines 33-36), but not, apparently, in the context of oral vaccine administration. Indeed, Koprowski describes experiments wherein mice were immunized with a bioactive compound orally or by injection; an adjuvant was used whenever the bioactive compound was administered by injection, but never when it was administered orally. See Examples 2 and 3.

Similarly, Stites merely teaches that "[a] quantity of antigen that is ineffective when injected intravenously may evoke a copious antibody response if injected subcutaneously in adjuvant," and that "[a]djuvants function in one or more of the following ways: (1) by prolonging retention of the immunogen, (2) by increasing its effective size, or (3) by stimulating the influx of . . . macrophages and/or lymphocytes" (page 102). The examiner has not explained how these teachings are relevant to orally administered vaccines.

Clearly, the examiner has established that individual parts of the claimed invention were known in the prior art. However, as explained in In re Kotzab, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000) (citations omitted):

> A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art

> references and the then-accepted wisdom in the field. [ ] Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher." [ ]
>
> Most if not all inventions arise from a combination of old elements. [ ] Thus, every element of a claimed invention may often be found in the prior art. [ ] However, identification in the prior art of each individual part claimed is insufficient to defeat patentability of the whole claimed invention. [ ] Rather, to establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant.

"It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992), citing In re Gorman, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). The examiner may establish a case of prima facie obviousness based on a combination of references "only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." Id., 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992).

The fact that the prior art could have been modified in a manner consistent with appellants' claims would not have made the modification obvious unless the prior art suggested the desirability of the modification. In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). On this record, the only reason or suggestion to combine the references in the manner claimed comes from appellant's specification.

Nor are we persuaded by the examiner's assertion that "one of ordinary skill would have had a reasonable expectation of success . . . [in] providing the claimed

functional effect of raising . . . [a] response greater than the response caused by HBSAG alone" (Answer, page 6). An expectation of success is an element in a prima facie case of obviousness, but it is not enough in the absence of a reason to modify the references in the first place.

The rejection of claims 1 and 4-18 under 35 U.S.C. § 103 is reversed.

REVERSED

Sherman D. Winters
Administrative Patent Judge

Toni R. Scheiner
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

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